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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,782	08/13/2001	Robert O. Ralston	154.206	1144

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,782

Applicant(s)

RALSTON ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-23 and 69-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-23 and 69-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the after final amendment filed October 12, 2004.

The finality of the previous action is hereby withdrawn.

Claims 20- 23 and 69- 79 are under consideration in this action.

Claim Objections

Claim 21 is objected to because of the following informalities: GNA should be spelled out. Appropriate correction is required.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

Claims 20- 23 and 69- 79 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is withdrawn after consideration of the written description rejection.

Claims 20- 23 and 69- 79 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the claims and the rejection is moot.

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Claims 20- 23, and 69- 79 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's argument concerning Example 16 of the Guidelines is found persuasive and the rejection is withdrawn.

Claims 20- 23, and 56- 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antigen production, does not reasonably provide enablement for specific antibodies and were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for concept of using an antigen to make an antibody, does not reasonably provide enablement for making an antibody for the stated antigen.

In light of the withdrawal of the Written Description Rejection above this rejection is also withdrawn.

New Rejections

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 20- 23, and 69- 79 are rejected under 35 U.S.C. 102(b) as anticipated by Houghton *et al.* (EP 318 216).

The claims are drawn to a kit comprising an antibody to asialated E1/E2. The kit is treated as a product and the product that adds patentable weight to the claims is the antibody. It is also noted that antibodies bind to the peptide structure of an epitope, glycosilation will affect binding, but antibodies still bind to the base peptide.

Applicant's previous argument is reconsidered.

Houghton discloses an isolated antibody that is reactive with HCV.

Applicant had argued that the example did not include the E1/E2 genes.

The reference claims antibodies, kits for detecting HCV with antibodies and HCV antibodies bound to a solid support. (claims 18, 19, 23 , and 26) and teaches that kits comprising the E antibody would be useful for detection (page 20, lines 43-49).

Thus, Houghton *et al.* anticipate the claimed invention.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 20- 23 and 69- 79 are rejected under 35 U.S.C. 102(a) as being anticipated by Houghton *et al.* (EP 388232).

The claims are drawn to a kit comprising an antibody to asialated E1/E2. The kit is treated as a product and the product that adds patentable weight to the claims is the antibody. It is also noted that antibodies bind to the peptide structure of an epitope, glycosilation will affect binding, but antibodies still bind to the base peptide.

Houghton discloses an isolated antibody that is reactive with HCV.

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The reference claims antibodies, kits for detecting HCV with antibodies and HCV antibodies bound to a solid support. (Claims 13, 14, and 17) and teaches that kits can be used for detection (page 21) and identifies E proteins (pages 32 and 34).

Thus, Houghton *et al.* anticipate the claimed invention.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20- 23 and 69- 79 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta *et al.* US005308750A.

The claims are drawn to a kit comprising an antibody to asialated E1/E2. The kit is treated as a product and the product that adds patentable weight to the claims is the antibody. It is also noted that antibodies bind to the peptide structure of an epitope, glycosilation will affect binding, but antibodies still bind to the base peptide.

Mehta *et al.* claim antibodies to the E2 of HCV for detection of HCV (claims 1-4). The patent also discloses antibodies to the E1 region (HCV env) (columns 5 and 6). The

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issued patent indicates that it is a CIP of the earlier applications; however, the file indicates that they are file wrapper continuations.

Thus, Mehta *et al.* anticipate the claimed invention.

Conclusion

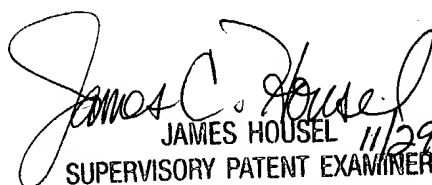
All claims are rejected.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.




JAMES HOUSEL 11/29/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600